REMARKS

Claims 6-11 and 13-17 are pending in this application. Claims 1-5, 12 and 18-24 have been canceled without prejudice or disclaimer. Applicants, by canceling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

I. At page 3 of the Official Action, claims 11-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Postma et al. and Maesen et al.

The Examiner asserts that Postma et al. describes the use of the R-epimer of ciclesonide in a powder inhaler for the treatment of asthma. The Examiner further asserts that Maesen et al. describes the use of formoterol for the treatment of airway diseases, and that it would have been obvious to combine the two compositions for the treatment of airway diseases.

In view of the following, Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04–1350, 550 U. S. ____ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the

design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, *supra*, slip opinion at 13-15). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants respectfully submit that a prima facie case of obviousness has not been established because, whether taken alone or in combination, neither Postma et al. or Maesen et al. teach or suggest each and every limitation of the presently pending claims as required by *In re Wilson.*

Independent claim 11 is directed to "a method of treating an airway disease in a patient comprising administering to a patient in need thereof a therapeutically effective amount of the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof in free combination and in an administration form suitable for inhalative administration by means of a powder inhaler with the active compound R,R-formoterol or a hydrate,

solvate, salt, hydrate of a salt or solvate of a salt thereof, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present in separate pack units, wherein it is possible to take out the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, from the separate pack units such that they are available for successive inhalative administration." Claim 12 has been canceled. Claims 13 and 15-17 depend, either directly or indirectly from claim 11. Claims 14 depends from claim 6.

In contrast, Postma et al. is directed towards a determination of whether the time point of administration (either morning or evening) affects the efficacy of ciclesonide in the treatment of asthma. *See* Postma et al. at page 1.

However, Postma et al. does not teach or suggest a method of treating an airway disease in a patient comprising administering to a patient in need thereof a therapeutically effective amount of ciclesonide and R,R-formoterol, wherein ciclesonide and R,R-formoterol are present in separate pack units such that they are available for successive inhalative administration, as required by pending claim 11.

In further contrast, Maesen et al. is directed towards an investigation of the effects of formoterol on exsmokers having chronic obstructive pulmonary disease. *See* Maesen et al. at page 1.

Neither Postma et al. nor Maesen et al., either taken alone or in combination, teach or suggest all the elements of presently pending claims, as required by *In re Wilson*. In particular, neither Postma et al. nor Maesen et al. teach or suggest a method of treating an airway disease comprising administering to a patient a composition containing both ciclesonide and R,R-formoterol, present in separate pack units such that they are available for successive inhalative administration, as required by pending claim 11.

As such, the Examiner has failed to demonstrate a *prima facie* case of obviousness against pending claims 11-17. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

II. At page 5 of the Official Action, claims 6-11 and 13-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Magee et al. (U.S. Patent Application No. 2002/0111495) in view of Calatayud et al. (U.S. Patent No. 5,482,934).

The Examiner asserts that Magee et al. (U.S. Patent Application No. 2002/0111495) describes the use of PDE4 inhibitors in a composition together with one or more therapeutic agents, including formoterol and ciclesonide for the treatment of airway diseases. Further, the Examiner asserts that Calatayud et al. (U.S. Patent No. 5,482,934) describes the synthesis of a general class of steroids and the purification to obtain either of the epimers, and that it would have been obvious to one of skill in the art to combine the composition as described in Magee et al. with the R-epimer of ciclesonide as described by Calatayud et al. to arrive at the presently claimed subject matter.

Applicants respectfully traverse this rejection because a *prima facie* case of obviousness has not been established.

A brief outline of relevant authority is set forth above in Section I.

Independent claim 6 is directed towards "a pharmaceutical composition comprising the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or a solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, in free combination and in an administration form suitable for inhalative administration by means of a powder inhaler, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present in separate pack units, wherein it is possible to take out the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, from the separate pack units such that they are available for successive inhalative administration." Claims 7-10 depend, either directly or indirectly, from claim 6.

Independent claim 11 is discussed above in Section 1 in regard to the previous rejection. Claims 13 and 15-17 depend, either directly or indirectly from claim 11. Claim 14 depends from claim 6.

In contrast to the subject matter of the presently pending claims, Magee et al. describes the use of a compound selected from a general class of PDE4 inhibitors used

in combination with other therapeutic agents, including formoterol and ciclesonide. Accordingly, Magee et al. require the combination of a PDE4 inhibitor with an additional active agent such as ciclesonide or formoterol. As such, it does not disclose a combination of ciclesonide and R,R-formoterol, as presently claimed. In further contrast, Calatayud et al. describes the synthesis of a general class of steroids that read on the structure of ciclesonide. Calatayud et al. also describes the purification of the mixture of epimers to obtain either of the epimers in a proportion of at least 99.9%.

However, none of the cited references, either alone or in combination, teach or suggest all the elements of the presently pending claims, as required by *In re Wilson*. In particular, neither Magee et al. nor Calatayud et al., either taken alone or in combination teach or suggest a composition containing both ciclesonide and R,R-formoterol, present in separate pack units such that they are available for successive inhalative administration, as recited in pending claim 6. Further, none of the cited references, either taken alone or in combination, teach or suggest a method of treating an airway disease comprising administering to a patient a therapeutically effective amount of ciclesonide and R,R-formoterol, present in separate pack units such that they are available for successive inhalative administration, as recited in pending claim 11.

As such, the cited references do not render the pending claims obvious within the meaning of 35 U.S.C. § 103(a). Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

III. At page 8 of the Official Action, claims 6-11 and 13-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Keller et al. (U.S. Patent No. 6,645,466), in view of Magee et al. and further in view of Calatayud et al.

The Examiner asserts that Keller et al. describes dry powder inhaler compositions that may contain formoterol or ciclesonide, and that it would have been obvious to a person skilled in the art to substitute the R-epimer of ciclesonide as described in Calatayud et al. into the compositions described in Keller et al. and use them for the treatment of airway diseases as described in Magee et al. to arrive at the presently claimed subject matter.

Applicants respectfully traverse this rejection because a *prima facie* case of obviousness has not been established.

A brief outline of relevant authority is set forth above in Section I.

Independent claim 6 is discussed above in regard to the previous rejection. Claims 7-10 depend, either directly or indirectly, from claim 6.

Independent claim 11 is discussed above in Section I in regard to the previous rejection. Claims 13 and 15-17 depend, either directly or indirectly, from claim 11. Claim 14 depends from claim 6.

In contrast to the subject matter of the presently pending claims, Keller et al. describes improved moisture resistant dry powder formulations for inhalation which contain an active compound. According to Keller et al., magnesium stearate is used in the dry powder formulations. *See* Keller et al. at the Abstract. Magee et al. and Calatayud et al. are discussed above in regard to the previous rejection.

None of the cited references, either alone or in combination, teach or suggest all the elements of the presently pending claims, as required by *In re Wilson*. In particular, neither Magee et al. nor Calatayud et al., either taken alone or in combination teach or

suggest a composition containing both ciclesonide and R,R-formoterol, present in separate pack units such that they are available for successive inhalative administration, as recited in pending claim 6. Further, none of the cited references, either taken alone or in combination, teach or suggest a method of treating an airway disease comprising administering to a patient a therapeutically effective amount of ciclesonide and R,R-formoterol, present in separate pack units such that they are available for successive inhalative administration, as recited in pending claim 11.

As such, the cited references do not render the pending claims obvious within the meaning of 35 U.S.C. § 103(a). Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

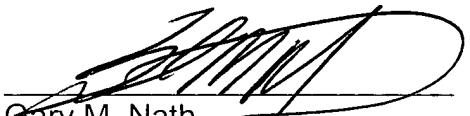
Conclusion

The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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Date: August 12, 2008
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